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JAN 2 4 2002

510 (k) Summary

Hemochron® Jr. Citrate Activate Partial Thromboplastin Time (APTT) Cuvette

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K014008

Prepared: November 29, 2001

Submitted by: John Clay
International Technidyne Corp.
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Device Name

Common / Usual Name: Activated Partial Thromboplastin Time

Product Name: Hemochron® Jr. Citrate APTT Cuvette

Predicate Device

The "modified" Hemochron Jr. Citrate APTT, which is the subject of this special 510(k) is a modification of the predicate Hemochron Jr. Citrate APTT, which was cleared under **K972831.**

Device Description and Technological Characteristics

The Hemochron Jr.Citrate APTT test is a self-contained disposable test cuvette, pre-filled with dried reagents required to perform an Activated Partial Thromboplastin Time (APTT) using citrated whole blood in the Hemochron Jr. Whole Blood Microcoagulation Analyzers. The preparation consists of kaolin, phospholipid, stabilizers and buffers. These same components are used in the previous formulation of the citrate APTT. The citrate APTT test can be performed on both the Hemochron Jr. II and Hemochron Jr. Signature Series instruments. The test is intended for point of care use.

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The instrument draws a precise volume of blood into the test channel of the cuvette, which contains the APTT reagent formulation. An array of LED's detects the motion of the blood sample/reagent mixtures as it moves through the precision restriction in the cuvette channel. The blood is pumped back and forth until a clot begins to form, obstructing the channel and slowing the flow of the blood sample. The instrument detects a clot when the blood movement decreases below a predetermined rate.

Modifications to the Predicate Hemochron Jr Citrate APTT Cuvette

Formulation

The only modification to the citrate APTT cuvette is to the reagent formulation, specifically, the optimization of the phospholipid concentration and the reduction of the concentration of calcium salts required for re-calcification of the citrated whole blood sample. The modification to the formula improves the correlation to the laboratory APTT Plasma result when either 3.2% or 3.8% sodium citrate tubes are used for the blood sample collection.

The modifications to the Citrate APTT described herein do not change the indications for use or the fundamental technology used in the previously cleared system.

Statement of Intended Use

The Hemochron Jr. Citrate APTT is a unitized microcoagulation test intended to be used in performing a quantitative one-stage Activated Partial Thromboplastin Time (APTT for monitoring low doses of heparin anticoagulation (up to 1.5 units/ml). The test is performed using a citrated whole blood sample on the Hemochron Jr. microcoagulation instruments. The test is intended for use in point of care settings.

For In Vitro Diagnostic Use Only

Summary of Performance Data and Precision

The laboratory correlation was generated using fresh citrated blood samples (n=210) from patients undergoing cardiac catheterization and angioplasty. Samples were analyzed at the patient bedside using the "modified" Hemochron Jr. Citrate APTT. An aliquot of the sample was mixed with sodium citrate, centrifuged and plasma was sent to a reference lab where a plasma APTT test was performed on each sample collected using Dade Actin FSL* APTT reagent on an Electra 900 MLA instrument.

Additional clinical studies were conducted to confirm the correlation to the laboratory result. The Hemochron Jr. APTT plasma equivalent values were highly correlated to the laboratory plasma citrate APTT values **(R=0.88)** with a correlation equation of **y=0.77x+8.57**.

In House Precision Testing

Precision testing was evaluated by performing multiple citrate APTT tests using two levels of standard whole blood control preparations, which have been selected to represent normal donors (Level I) and patients receiving heparin anticoagulant (Level II). Two different lots of Citrate APTT test cuvettes were used in the precision study and testing was performed on three separate days.

PRECISION DATA

Cuvette Lot 1

	N	Normal Mean (sec)	SD (sec)	CV (%)	N
Day 1	3	95	6.5	6.9	3
Day 2	3	92	2.1	2.3	3
Day 3	3	86	5.0	5.9	3
Total	9	91	5.9	6.4	9

Cuvette Lot 2

	N	Normal Mean (sec)	SD (sec)	CV (%)	N
Day 1	3	94	1.0	1.1	3
Day 2	3	99	5.9	5.9	3
Day 3	3	90	6.1	6.8	3
Total	9	95	5.8	6.1	9

Conclusion

The technology employed and intended use of the modified Hemochron Jr.Citrate APTT cuvette is substantially equivalent to the Predicate Hemochron Jr. Citrate APTT. This modification to the formula improves the correlation to the laboratory APTT Plasma result when either 3.2% or 3.8% sodium citrate tubes are used for the blood sample collection.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. John Clay
Regulatory Affairs Manager
ITC, Inc.
8 Olsen Avenue
Edison, NJ 08820

JAN 2 4 2002

Re: k014008
Trade/Device Name: Hemochron® Jr. Citrate APTT cuvette
Regulation Number: 21 CFR 864.7925
Regulation Name: Partial thromboplastin time tests
Regulatory Class: Class II
Product Code: GFO
Dated: January 16, 2002
Received: January 17, 2002

Dear Mr. Clay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (If Known): K014008

Device Name: Hemochron® Jr. Citrate APTT cuvette
Indications for Use:

The Hemochron Jr. Citrate APTT is a unitized microcoagulation test intended to be used in performing a quantitative one-stage Activated Partial Thromboplastin Time (APTT for monitoring low doses of heparin anticoagulation (up to 1.5 units/ml). The test is performed using a citrated whole blood sample on the Hemochron Jr. microcoagulation instruments. The test is intended for use in point of care settings.

For In Vitro Diagnostic Use Only

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K014008

Prescription Use ✓ or Over- the- Counter Use_____
Per 21 CFR 801.109

(Optional Format 1-2-96)